



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/029,359 | 12/21/2001 | Anneli Attersand | 10806-156 | 4324 |

24256 7590 07/15/2003

DINSMORE & SHOHL, LLP
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER

MAYES, LAURIE A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

DATE MAILED: 07/15/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,359

Applicant(s)

ATTERSAND, ANNELI

Examiner

Laurie Mayes

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 15 is acknowledged. The traversal is on the ground(s) that claim 8 is directed to a method which comprises providing a cell comprising the nucleic acid molecule of claim 1. This is not found persuasive because the method in Group I requires different steps and has a different purpose than the method of Group III as the method of Group I involves the use of a vector and a host cell in the recombinant production of a protein while the method of Group III involves contacting a nucleic acid molecule and an agent to see if the agent modifies the nucleic acid molecule. As the methods have different purposes and steps, a search of each method would require different searches.

The requirement is still deemed proper and is therefore made FINAL. As claims 2, 3 and 8 are drawn to non-elected groups, only claims 1, 4-7, 9 and 10 are examined.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (p. 8, first and second paragraphs; p. 9p. 10, third and fourth paragraphs; p. 11, last paragraph; p. 12, first and third paragraphs). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The use of the trademarks INCYTE LIFESEQ (p. 11, last paragraph), MTN (p. 12, first paragraph) and GENECHIP (p. 12, third paragraph) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Art Unit: 1653

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 3 is objected to because of the following informalities: The claim must end with a period ".". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4-7, 9 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The claimed invention lacks patentable utility. The applicant's invention is for a nucleic acid molecule which encode "Protein Cluster II" and which are predicted to be useful in the diagnosis of metabolic diseases (specification, p. 1, first paragraph). However, the applicant fails to describe how the molecule would be useful regarding metabolic diseases, whether as use in a pharmaceutical preparation or use to diagnose diabetes, nor has the applicant described how to use or administer the nucleic acid in such treatment, diagnosis or other actual use. Further, the applicant states (p. 8 of specification, last two lines) that the protein encoded by the nucleic acid molecule has an "unknown function".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-7, 9 and 10 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Birren et al.

(AC009938; 08-Sep-1999, Whitehead Institute/ MIT Center for Genome Research, 320 Charles Street, Cambridge, MA 02141). Birren et al. teach a nucleic acid sequence with nearly 100% identity to SEQ ID NO: 1 wherein Birren et al.'s sequence comprises a nucleotide sequence that is found within SEQ ID NO:1. The language in claim 1 "nucleic acid molecules comprising a nucleotide sequence as shown in SEQ ID NOL 1" includes smaller sequences that are found within SEQ ID NO:1. Thus, Birren et al. teach all of the elements of claim 1 and this claim is anticipated by 35 U.S.C. 102(b).

Art Unit: 1653

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albertini et al. (US 6,113,903) in view of Birren et al. Albertini et al. teach a method of treating the metabolic disorder diabetes using vectors having an expression control sequence operatively linked to a nucleic acid molecule where it directs the transcription and translation in a host cell and a making a polypeptide (col. 9, lines 1-21). Albertini et al. do not teach a sequence comprising SEQ ID NO: 1.

Birren et al. teach a nucleic acid sequence with nearly 100% identity to SEQ ID NO: 1 wherein Birren et al.'s sequence comprises a nucleotide sequence that is found within SEQ ID NO:1. Birren et al. do not teach a vector, host cell or method of making a protein by recombinant means.

Given the advantages of being able to recombinantly produce a specific protein and the successful method of making a metabolically effecting protein by recombinant means as taught by Albertini et al., it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use the nucleic acid molecule as taught by Birren et al. to make a corresponding vector and host cell and the use recombinant means to express the corresponding protein. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Art Unit: 1653

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Laurie Mayes
Patent Examiner
Art Unit 1653
July 2, 2003


CHRISTOPHER S. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600